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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,423	03/10/2005	Albert Duranton	122005	2517

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EXAMINER	
YU, GINA C	

ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
12/01/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/517,423	DURANTON ET AL.	
	Examiner	Art Unit	
	GINA C. YU	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2010 and 01 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-15 and 19-46* is/are pending in the application.

4a) Of the above claim(s) *27-38 and 42-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6, 8-15, 19-26, 39-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *November 9, 2009 and March 1, 2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 1, 2010 has been entered.

Supplemental amendment filed on April 1, 2010 has been entered.

Election/Restrictions

Amended claims 12, 14, 22-25 further limit claim 1 and read on the elected species (polyphenol) which is a required component in the base claim. Thus, claims 12, 14 and 22-25 are rejoined and examined on the merits. See Applicant's Remarks mailed on March 1, 2010, p. 3.

In supplemental remarks filed on April 1, 2010, applicant further requests that claims 47-38 and 42-46 are rejoined, asserting unity of invention between these claims and the claims that have been examined on the merits. Applicant argues that all claims share at least one technical feature that distinguishes over the art, which is the combination of (1) at least one of taurine, hypotaurine, salts of taurine and salts of hypotaurine, and (2) at least one polyphenol, and asserts the combination is a allowable subject matter. However, prior arts of the record indicates that such combination lacks inventive concept and does not satisfy the requirement for unity of invention. See rejections below.

Therefore, claims 1-6, 8-15, 19-26, 39-41 are examined on the merits.

Claims 27-38 and 42-46 are withdrawn from consideration.

Oath/Declaration

Declaration filed under 37 C.F.R. § 1.132 has been fully considered but does not place the application in allowable condition.

Declarant states that administering the combination of taurine and polyphenols produce unexpected results of taurine/polyphenol combination. Declaration indicates that taurine, polyphenols from green tea, and the combination of taurine and polyphenols were tested for their respective efficacy in inhibition of "the amount of proline-rich proteins) that were synthesized

and secreted by Normal Human Dermal Fibroblast ("NHDF") cells. According to the declarant, the test results show that taurine or the polyphenol alone does not significantly inhibit the amount of proline-rich proteins, while the combination of taurine and polyphenols inhibited hyperproduction of both newly synthesized proline-rich proteins and secreted proline-rich proteins.

In the remarks filed on March 1, 2010, applicant asserts that fibroblasts have the ability to synthesize collagen, which is a proline, and inhibition of collagen metabolism "is a mechanism for treating a reducing the likelihood of developing alopecia". Applicant thus concludes that administering taurine/polyphenols treats or reduces the likelihood of developing alopecia.

However, data is not commensurate with the scope of the present claims, as the polyphenols from green tea constitute a unique composition of specific type of phenols. The typical percentage of the individual catechins (polyphenols) in green tea extracts is 10-15 % epicatechin, 2-3 % gallocatechin, 2 % epicatechin, 2-3 % epigallocatechin. See Morre et al. (US 6428, 818 B1), col. 12, lines 5-8, citing Suganuma et al., 1999, Can. Res. 59:44-47. See also applicant's specification, p. 41. Declarant's conclusion that any species from the genus of polyphenols is expected to achieve the similar result lacks support.

Furthermore, the current data indicates that at 1 and 5 mM concentration of taurine alone did not significantly affect proline incorporation, which is inconsistent with the disclosure in specification, which reports that a significant inhibition at 1 mM was observed. See Declaration p. 5; specification, p. 26. There is no explanation provided in the declaration to cure the inconsistency.

Thus, the declaration fails to place the present application in allowable condition.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 2-4 recite various effects that may result from orally administering a composition comprising at least one of taurine, hypotaurine, salts of taurine and salts of hypotaurine, and at least one polyphenol in an amount effect for treating or reducing the likelihood of miniaturization of the hair follicle and/or alopecia. The composition specifically excludes amino acids other than the taurine component. The specification fails to convey a skilled artisan that applicant was in possession of the methods of claims 2-4. Although the specification shows an in vitro test that shows taurine inhibits incorporation of proline by fibroblasts and example formulations of the oral compositions according to the claims, there is not sufficient disclosure in the specification to support that administering taurine to a human will result as stated in instant claims 2-4. Thus, claims 2-4 fail to meet written description requirement.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 8-15, 19-26, 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "a method of treating or reducing the likelihood of miniaturization of the hair follicle and/or alopecia". Claim 1 is vague and indefinite, as it is unclear which methods are encompassed by the alternative expressions. The claim encompasses a) a method of treating miniaturization of the hair follicles and/or alopecia; b) a method of reducing ***the likelihood*** of miniaturization of the hair follicles and/or alopecia. It is not clear what applicant means by reducing the possibility of these conditions that have not yet occurred. The remaining claims are rejected as they depend on the definite base claim.

Claim 41 depends on claim 39 which requires polyphenols. The dependent claim however additionally requires at least one supplement which may be polyphenols. Such

limitation fails to further limit the base claim, and renders claim 41 vague and indefinite, as it is not clear whether the dependent claim requires a different type of polyphenol from the polyphenol of the base claim.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-6, 8-11, 13-15, 19-26, 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamada et al. (JP 2002-097116, Machine translation) in view of Kung (US 5639785) and McCarty (US 5582839).

Hamada teaches that taurine acts as a cellular activator for regulating hair cells and discloses hair-stimulating compositions for topical application.

Hamada fails to teach oral administration of taurine.

Kung teaches pharmaceutical compositions of isoflavanoid derivatives (polyphenols) for the treatment of male pattern baldness and alopecia areata, and in promoting the conversion of gray hair to the original pigment in hair follicles. See abstract. The reference indicates that it is well known and conventional practice in pharmaceutical art to administer active compounds in various routes via oral and topical formulations, among others. See col. 4, lines 31-46. Specific types of formulations including tablets, capsules, powders, soft gels, solutions, emulsions, creams or ointments are mentioned. The reference teaches that both topical and oral administration of Minoxidil and daidzein treat baldness. See col. 1, lines 16-29. As for the dosage and the effective amount of daidzein, the reference indicates that the quantity will vary depending on the patient and the mode of administration. The reference indicates that from about 0.001-20 mg/kg of body weight of the patient per day may be used to achieve the desired effect. See col. 4, lines 46-56.

While Hamada and Kung do not specifically disclose orally administrable form of taurine, oral formulation of a highly soluble mineral salt of taurine, such as magnesium taurate, is already well-known in pharmaceutical art. See McCarty, col. 3, lines 5-23.

It would have been obvious to one of ordinary skill in the art at the time of the present invention to modify the teaching of Hamada by formulating orally administrable compositions as motivated by Kung because 1) Hamada teaches using taurine to treat alopecia; 2) Kung teaches

that designing both topical and oral formulations of anti-alopecia compounds such as Minoxidil and diadzien is well known in the art; and 3) McCarty teaches that oral administration of taurine salt already had been in practice.

As for the suitable amount of taurine in the composition, differences in concentration generally will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In this case, prior arts provides general condition of making the drug since Hamada teaches a suitable amount of taurine in topical formulation in treating alopecia and Kung and McCarty teach oral formulation. Given these teachings, discovering an optimal weight of the active ingredient would have been within the skill of the art.

Claims 12, 14, 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamada, Kung and McCarty as applied to claims 1-6, 8-11, 13-15, 19-21, 39-41 as above, and further in view of Ruan (CN 1309926 A, abstract).

The combined references do not teach fatty acids.

Ruan teaches that natural oil extracted from seed and leaf of oriented arborvitae is rich in linoleic acid and gamma-linolenic acid with the health function of treating alopecia, lowering blood lipoid, dissolving thrombus and reducing cholesterol. See abstract. The reference further teaches that the oil is used in food, medicine and cosmetics.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of the combined references by further incorporating to the taurine/polyphenol combination fatty acids such as linoleic acid and gamma-linolenic acid as motivated by Ruan because the latter teaches the specific utility of these fatty acids as anti-alopecia agents. Since all the references teach a method of treating alopecia and Ruan teaches using the fatty acids in food and medicine, the skilled artisan would have had a reasonable expectation of successfully treating alopecia.

Response to Arguments

Applicant's arguments filed on March 1, 2010 have been fully considered but they are not persuasive for reasons stated in Oath/Declaration above.

Applicant's remarks filed on April 1, 2010 have been fully considered but they are not persuasive for reasons stated in Election/Restriction above.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINA C. YU whose telephone number is (571)272-8605. The examiner can normally be reached on Monday through Thursday, from 8:00AM until 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydou G. Sajjadi at 571-272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GINA C. YU/
Primary Examiner, Art Unit 1617